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U.S.S.N. 10/804,787
Filed: March 19, 2004
AMENDMENT AND RESPONSE TO OFFICE ACTION

Remarks

Rejection Under 35 U.S.C. § 102

Claims 2-6, 8, 9, 11, 12, 41, 48, 49, and 51-54 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,250,613 to Bergstrom *et al.* ("Bergstrom"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Independent Claims 41 and 48

Claims 41 and 48 have been amended to specify the form of the block copolymer, and to further specify that when the block copolymer is in the form of a brush copolymer, the cationic block is not a polyethylene imine. Support for this amendment can be found in the specification at least at page 6, lines 12-13, 15-23 (block copolymers, brush copolymers and dendritic copolymers) and page 7, lines 2-3 (brush copolymers); page 8, lines 20-23; page 9, lines 5-6 (dendritic copolymers); page 18, lines 5-12 (linear copolymers).

The Manual for Patent Examining Procedure states that "any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims" (MPEP 2173.05(i)). Applicants disclose that the polycationic blocks include a long list of polymers, and specifically mention "polyethyleneimine" at page 7, line 26. Therefore, the disclaimer of polyethylene imine in claims 41 and 48 is supported by the specification.

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Bergstrom

Bergstrom discloses forming polymeric conjugates containing (1) polyethyleneimine covalently attached to (2) a nonionic, hydrophilic polymer (e.g. polyethylene glycol), which is covalently attached to (3) a biopolymer (e.g. a protein). In one embodiment, after these conjugates are formed, they are adsorbed onto a negatively charged surface (*see* col. 4, lines 62-63).

The copolymer in Bergstrom is based on a polyethylene imine (PEI) homopolymer skeleton. No other backbones are disclosed in Bergstrom. PEI contains secondary, tertiary and primary amino groups (*see* col. 7, lines 41-47). Consequently, the PEI backbone will be branched, thereby forming a brush copolymer with the polyethylene glycol groups.

In contrast, independent claim 41 and 48, as amended, specify that the coating is formed of a block copolymer in the form of a brush copolymer, dendritic copolymer or linear copolymer, where the copolymer contains a polycationic block comprising either a linear polycationic block or a dendritic polycationic block with a molecular weight sufficient to provide at least eight cationic charges. Bergstrom does not disclose linear or dendritic copolymers. Dendrimers are defined in the specification as "polymers which include a core molecule which is sequentially reacted with monomers with three or more reactive groups, such that at each sequential coupling step, the number of reactive groups at the ends of the polymer increases, usually exponentially." (page 6, lines 20-23). As noted above, Bergstrom's disclosure is limited to brush block copolymers containing a homopolymeric PEI backbone.

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With respect to brush copolymers, claims 41 and 48, as amended, specify that when the copolymer is in the form of a brush copolymer, the polycationic block is not polyethylene imine. Therefore, claims 41 and 48 exclude the block copolymer described in Bergstrom.

Therefore, Bergstrom does not disclose the claimed medical devices or implants or methods for coating the surface of a medical device or implant, as defined in claims 41 and 48 and their dependent claims. Therefore claims 2-6, 8, 9, 11, 12, 41, 48, 49, and 51-54, as amended, are novel in view of Bergstrom.

Rejection Under 35 U.S.C. § 103

Claims 7, 42, and 50 were rejected under 35 U.S.C. § 103(a) as being obvious over Bergstrom. Applicants respectfully traverse this rejection.

Claim 7 is not obvious

Claim 7 depends from claim 48 and specifies that the polycationic block contains lysine, histidine, arginine or ornithine monomeric units. As noted above, Bergstrom's disclosure is limited to copolymers based on a polyethylene imine (PEI) skeleton. Bergstrom contains no disclosure or suggestion to modify its copolymers so that the polycationic block contains lysine, histidine, arginine or ornithine, as required by claim 7. Further, Bergstrom contains no disclosure or suggestion to modify its copolymers to be in the form of a linear copolymer, dendritic copolymer or a brush copolymer, as defined by dependent claim 7. Therefore claim 7 is not obvious in view of Bergstrom.

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AMENDMENT AND RESPONSE TO OFFICE ACTION***Claims 42 and 50 are not obvious***

Claims 42 and 50 depend from claims 41 and 48, respectively, and specify that the surface of the implant or medical device is metal. Bergstrom discloses that the surface to which its PEI polymer can be adsorbed is a silica or glass surface or a polymeric surface upon which a negative charge is induced using acidic etching (see col. 4, lines 64-68). There is no disclosure or suggestion in Bergstrom to modify its coatings so that they are on a metal surface and are formed of a copolymer in the form of a linear copolymer, dendritic copolymer or a brush copolymer, as defined by dependent claims 42 and 50. Therefore claims 42 and 50 are not obvious in view of Bergstrom.

Double Patenting Rejection

Claims 2-9, 11, 12, 41, 42, and 48-52 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,743,521 to Hubbell *et al.*, in view of Bergstrom or U.S. Patent No. 6,013,855 to McPherson *et al.* ("McPherson"). Applicants will submit a terminal disclaimer to overcome this double patenting rejection when the claims are determined to be otherwise patentable.

Additional Amendments to the Claims

Claims 49, 50 and 52 have been amended to clarify that the surface is a glass or metal surface. Support for these amendments can be found in claim 42 as originally filed and page 22, lines 4-5 (metal surface) and page 21, lines 19-24 (glass surface).

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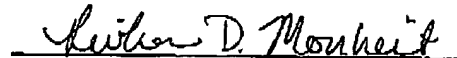
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Allowance of claims 2- 9, 11, 12, 41, 42, and 48-52, as amended, is respectfully solicited.

Respectfully submitted,



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